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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/392,842	09/09/1999	SAMUEL P. SAWAN	SUR-008	1863

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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/392,842	SAWAN ET AL.	
	Examiner	Art Unit	
	Kendra D. Carter	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58,60,62-71,89,91-94 and 96-125* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58,60,62-71,89,91-94 and 96-125* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 4, 2007 has been entered.

Claims 58, 60, 62-71, 89, 91-94 and 96-125 are pending in the application and are being examined on the merits herein. Claim 125 is new.

It is noted that the claims are being examined to the extent they read on the elected species of biguanide polymer (cationic polymer) that is poly(hexamethylenebiguanide) ("PHMB"), and the water-insoluble organic compound that is methylene-bis-N,N-diglycidylaniline, ("MBDGA").

The Examiner acknowledges Applicant's indication that a terminal disclaimer will be filed upon identification of allowable subject matter to obviate the provisional obviousness-type double patenting rejections over U.S. Patents 6,180,584; 6,030,632;

5,869,072 and 5,817,325. However, as such terminal disclaimers have not as-yet been filed, the provisional obviousness-type double patenting rejections over these co-pending applications are being maintained.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejection of claims 58, 60, 62-64, 68-71, 89, 92, 93, 96, 98-103, 105-106, 108-114 and 117-124 as being unpatentable over Morlet et al. in view of Fox, Jr., and further in view of Smith were found not persuasive, thus the rejection is upheld.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejection of claims 65-67, 91, 94, 97, 104,107 and 115-116 as being unpatentable over Morlet et al. in view of Fox, Jr., and further in view of Smith as applied to claims 58, 60, 62-64, 68-71, 89, 92, 93, 96, 98-103, 105-106, 108-114 and 117-124 above, and further in view of Sawan et al., were found not persuasive, thus the rejection is upheld.

In light of the new claim, the modified 35 U.S.C. 103(a) rejections and obviousness double patenting rejections are made below. Applicant's arguments are addressed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(1) Claims 58, 60, 62-64, 68-71, 89, 92, 93, 96, 98-103, 105-106, 108-114 and 117-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morlet et al (WO 97/00076), in view of Fox, Jr. (U.S. Patent No. 5,374,432), and further in view of Smith (U.S. Patent No. 5,576,006).

Morlet et al. teaches compositions comprising poly(hexamethylene biguanidine) salts in the topical treatment of microbial infections, as well as in pharmaceutical preparations and antiseptics (see abstract, in particular.) Morlet et al. teaches that PHMB has been discovered to be generally useful for the topical treatment of microbial infection of the human or animal body, such as on skin, as well as an antiseptic to clean skin (see page 3, lines 20-30, page 4, lines 18-25, and page 6, lines 30-35, in particular.) Morlet et al. teaches that compositions applied to the skin can comprise aqueous formulations, oily formulations, an oil-in-water emulsion, and a gel formulation,

among others, and thus teaches the carrier and formulation form as recited in claims 58, 89, 92, 103, 105 and 109 (see page 7, lines 3-8, in particular.) Morlet et al. also teaches that the composition can comprise excipients to adjust the viscosity (thickeners) (see page 9, lines 25-35, in particular), and thus teaches the skin-compatible component as recited in claim 93. Accordingly, Morlet et al. teaches a method for providing improved antimicrobial activity on skin comprising administering to the skin a composition comprising a polymer corresponding to the elected species of poly (hexamethylenebiguanide) (PHMB), as recited in claims 58, 89, 92, 93, 96, 98, 103 and 105.

Regarding claims 96, 98 and 108, it is noted the Moret et al. exemplifies bathing tissue in PHMB solution (see Example 4, in particular), and thus teaches that the composition can be administered by immersion, as recited in the claims.

Morlet et al. does not specifically teach administering to the skin a composition comprising an antimicrobial metallic material, as recited in claims 58, 89, 92, 93, 96, 98, 103 and 105. Morlet et al. also does not specifically teach forming a moisture-resistant film on the skin, as recited in claims 58, 89, 92, 93, 96, 98, 103 and 105. However, Morlet et al. does teach that the composition can comprise further pharmaceutically active substances, such as other compositions having antimicrobial activity (see page 10, lines 18-26, in particular.)

Fox teaches topical compositions having silver or a silver salt along with an antibiotic (see abstract, in particular.) Fox teaches that it is known to provide silver salts to prevent or reduce the infection of burn wounds, and that silver salts such as AgSD are known to be effective against a number of different types of bacteria (see column 1, lines 15-25, and column 2, lines 10-30, in particular.) Fox teaches that it has been further discovered that combinations of silver or silver salts with other antimicrobials provide improved antimicrobial efficacy, such that lower levels of the other antimicrobial agents can be provided (see column 1, lines 25-33 and column 2, lines 30-45, in particular.) Fox teaches that suitable silver salts include silver iodide and silver nitrate (see column 1, lines 60-66, in particular), and thus teaches the antimicrobial metallic materials as recited in claims 58, 89, 92, 93, 96, 98, 103 and 105. Fox teaches that composition having the silver or silver salt and antimicrobial agent can be administered for ocular infections as well as in the treatment of burn wounds (see column 2, lines 10-30, in particular), and thus Fox teaches that the silver or silver salts can be administered topically to skin.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the antimicrobial silver salt of Fox in the topical application method and composition of Morlet et al, because Morlet et al. teaches topically administering a composition having an antimicrobial agent for the treatment of microbial infections, and teaches the composition can also comprise other conventional antimicrobial agents, while Fox teaches that silver salts act as

antimicrobial agents, are suitable for topical compositions, and exhibit synergistic effects with other antimicrobials. Thus, it is considered that one of ordinary skill in the art would have been motivated to provide the silver salts in the method and composition of Morlet et al. with the expectation of formulating a composition having the desired antimicrobial effects and even having improved antimicrobial effects due to the synergism of the silver salts with the antimicrobial agent. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Morlet et al. and Fox do not specifically teach forming a moisture-resistant film on the skin, as recited in claims 58, 89, 92, 93, 96, 98, 103 and 105.

Smith teaches forming complexes of antimicrobial compounds that are less water soluble and more hypoallergenic (see abstract and column 1, lines 10-20, in particular.) Smith teaches that the complexes desirably form a more insoluble higher molecular weight molecule that posses the full activity of the smaller molecule, but are more resistant to being washed away, more hypoallergenic, and longer lasting, and thus allow a larger lasting effect without having to use the antimicrobial agent in higher dosages (see column 3, lines 10-25, in particular.) Smith teach that the complex can be used in

body compositions such as powders, lotions or salves used in treating the body (see column 2, lines 34-38, in particular.) Smith teaches that, in particular, the antimicrobial complexes can be forming with antimicrobial biguanide compounds, such as polyhexamethylene biguanide hydrochloride (see column 2, lines 55-60 and column 4, lines 10-15, in particular), and thus teaches forming a complex from the elected species of biguanide polymer. Smith further exemplifies a preparation having a COSMOCIL (polyhexamethylene biguanide hydrochloride) and citrate complex, in which the high molecular weight complex forms a film upon application to a surface (see Example 1, in particular.) Thus, Smith et al. teaches providing a polyhexamethylene biguanide complex that forms a moisture-resistant film, and thus imparts a persistant antimicrobial activity, as recited in claims 58, 89, 92, 93, 96, 98, 103 and 105.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the high molecular weight polyhexamethylene biguanide complex of Smith in the topical antimicrobial treatment method of Morlet et al. and Fox, because Morlet et al. and Fox teach that polyhexamethylene biguanide can be topically applied to skin to provide antimicrobial treatment, whereas Smith teaches that the antimicrobial use of polyhexamethylene biguanide, including use on the body, can be improved by forming a high molecular weight complex of the compound, which has higher water resistance, is more hypoallergenic, and is longer lasting. Thus, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the

polyhexamethylene biguanide complex in the method and composition of Morlet et al. and Fox, and thus to form a moisture-resistant film on the skin, with the expectation of providing improved antimicrobial activity that is longer lasting and more hypoallergenic. Accordingly, claims 58, 89, 92, 93, 96, 98, 103 and 105 are obvious over the teachings of Morlet et al. in view of Fox and Smith.

Regarding claims 60, 106 and 110-111, Morlet and Smith teach providing poly (hexamethylenebigaunide) and the hydrochloride salt thereof, as has been discussed above. Regarding claims 62-64, 101, 112-114 and 123, Fox teaches the silver salt can be silver nitrate or silver iodide, as discussed above.

Regarding claims 68-71 and 117-120, as Morlet et al. and Smith teach the same biguanide polymer as that of the instantly elected species, it is considered the Morlet et al. and Smith also teach a compound having the same chemical groups and the ability to form the covalent bonds at room temperature, as recited in the claims. It is noted that the a product and its properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Regarding claims 99-100 and 121-122, as Smith et al. teaches that the high-molecular complex of the biguanide polymer is water-resistant, it is considered that the film is also sweat resistant and does not leach into a contacting aqueous solution, as recited in the claims. Furthermore as the combined teachings of Morlet et al, Fox and

Smith renders the composition used in the claims method obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the sweat resistance and resistance to leachability, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Regarding claims 102 and 124, as the combined teachings of Morlet et al, Fox and Smith renders the obvious the use of the same metallic material as recited in the claimed method, is it considered that the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the binding of the metallic materials to the cellular proteins of microorganisms, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

(2) Claims 65-67, 91, 94, 97, 104,107, 115-116 and 125 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/00076 to Morlet et al, in view of U.S. Patent No. 5,374,432 to Charles L. Fox, Jr., issued December 20, 1994, and U.S. Patent No. 5,576,006 to W. Novis Smith, issued November 19, 1996, as applied to claims 58, 60, 62-64, 68-71, 89, 92, 93, 96, 98-103, 105-106, 108-114 and 117-124 above, and further in view of WO 95/17152 to Sawan et al, published Jun 29, 1995.

Morlet et al, Fox and Smith are applied as discussed above, and teach a method of providing antimicrobial activity on skin by applying a composition having the elected species of polyhexamethylene biguanide hydrochloride and an antimicrobial metallic material, such as silver nitrate or silver iodide. Smith furthermore teaches the desirability of complexing the polyhexamethylene biguanide hydrochloride with another compound to provide a high molecular weight compound. Smith teaches that the formation of a higher molecular weight compound provides a compound that is more insoluble and is longer lasting since the newly formed molecule has increased size. Thus, the compound has improved resistance to being washed away and improved hypoallergenicity, and has a longer lasting effect.(see column 3, lines 10-25 of Smith, in particular.) Smith also teaches an embodiment in which the improved antimicrobial composition forms a film (see Example 1, in particular.)

The references do not specifically teach forming an adduct of the biguanide with the elected species of substantially water-insoluble organic compound that is methylene-bis-N,N-diglycidylaniline, as recited in the claims.

Sawan et al. teaches that polyhexamethylene biguanide is known as an antibacterial and antimicrobial agent (see pages 19-20, in particular.) Sawan et al. also teaches that the antimicrobial compounds can be derivatized. Sawan et al. further teaches that a suitable antimicrobial combination that is effective against both bacteria and yeast can be a combination of silver and a biguanide compound (see page 22, first full paragraph, in particular.) Sawan et al. exemplifies an antimicrobial coating solution in which an adduct of polyhexamethylenebiguanide and 4,4-methylene-bi(N,N-diglycidylaniline) is formed (see Example 18, in particular), and thus teaches the elected species of substantially water-insoluble organic compound that is methylene-bis-N,N-diglycidylaniline, as recited in the claims. Sawan et al. also teaches silver iodide can be added to the exemplified solution (see Example 19, part (c), in particular.) Sawan et al. teaches that the antimicrobial compositions are suitable for sterilizing solutions such as eyecare liquids and other medicaments (see page 6 and page 9, in particular), and thus teaches that the antimicrobial compositions are safe for use with compositions meant for application to the body.

Accordingly, it is considered that one of ordinary skill in the art would have found it obvious at the time the invention was made to provide the PHMB and 4,4-methylene-bis(N,N-digylidylaniline) complex of Sawan et al. in the method and composition of Morlet et al, Fox and Smith, because Morlet et al, Fox and Smith teach the desirability of topically applying a composition having silver salts and PHMB to provide antimicrobial activity, and also teach that PHMB can be complexed with other compounds to provide a higher molecular weight compound that is longer lasting in its efficacy, and Sawan et al teaches a PHMB complex that provides antimicrobial activity, is safe for use with compositions that are applied to the body, and can be advantageously combined with silver salts. Thus, it is considered that one of ordinary skill in the art would have been motivated to provide the PHMB complex of Sawan et al. in the composition and method of Morlet et al, Fox and Smith, with the expectation of providing an improved antimicrobial composition and method having an antimicrobial PHMB complex that can be suitably combined with the silver salts therein, that is safe for application to the body, and that is a high molecular weight complex with longer lasting antimicrobial activity.

Furthermore, regarding the formation of a film on the skin with the composition, as recited in the claims, it is considered that as Morlet et al, Fox, Smith and Sawan et al. render the claimed composition and method of using obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the formation of the film, are inseparable from its composition.

Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product and process of using the product.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 58, 60, 62-71, 89, 91-94 and 96-125 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 6,180,584, claims 1-6 of U.S. Patent No. 6,030,632, claims 1-9 of U.S. Patent No. 5,869,072, and claims 1-9 of U.S. Patent No. 5,817,325. Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the cited patents are directed to compositions comprising a biguanide material, a metal material such as silver compounds and a cross linker and/or methods of using such composition to improve antimicrobial activity of an article or a secondary formulation.

For example, the claims of the patent 6,018,584 are directed to methods of providing antimicrobial activity on skin by applying the claimed invented disinfectant composition of a substrate (claims 1, 27-33.) The instant claims differ from the patented claims only by the nature of the substrate. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ the composition of the patented claims on suitable substrates including scrubs, skin preparations directly or through suitable carrier systems. Accordingly, the instant claims are an obvious modification of the already patented claims.

Response to Arguments

Applicant's arguments filed September 4, 2007 have been fully considered but they are not persuasive.

Claims 58, 60, 62-64, 68-71, 89, 92, 93, 96, 98-103, 105-106, 108-114 and 117-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morlet et al (WO 97/00076), in view of Fox, Jr. (U.S. Patent No. 5,374,432), and further in view of Smith (U.S. Patent No. 5,576,006).

The Applicant argues that there is no reason a person of ordinary skill in the art would form the specific combination of elements as recited in the present invention to be used in the method as claimed. In particular, there is nothing in Morlet or Fox to suggest combining the Morlet polymer composition with a metallic material or combining the Fox metallic material with an organic polycationic polymer to form the moisture-resistant films used in the present invention. The reason provided by the Examiner is insufficient for combining these references. A person of ordinary skill in the art would not have been motivated to vary all parameters to try each of numerous possible choices until one possibly arrived at a successful result. Neither Morlet nor Fox gave either no indication of which parameters were critical or no direction as to which of may possible choices is likely to be successful. In re Kerkohven does not apply to the present application. The present invention does not randomly combine two antimicrobials but provides an organic polycationic polymer in combination with an antimicrobial metallic material. Therefore, even before examiner the third reference (Smith) necessary to obtain each element of the claimed invention, the presently claimed invention is not obvious since the combination of an organic polycationic polymer with an antimicrobial metallic material for topical use is not obvious.

The Examiner disagrees because Morlet et al. and Fox et al. teach the desirability of providing topical antimicrobial compositions having the biguanide polymer and antimicrobial metallic material as claimed. Particularly, Morlet et al. teaches that PHMB has been discovered to be generally useful for the topical treatment of microbial infection of the human or animal body, such as on skin, as well as an antiseptic to clean skin (see page 3, lines 20-30, page 4, lines 18-25, and page 6, lines 30-35, in particular.) Fox et al. teaches that it is known to provide silver salts to prevent or reduce the infection of burn wounds, and that silver salts such as AgSD are known to be effective against a number of different types of bacteria (see column 1, lines 15-25, and column 2, lines 10-30, in particular.) Fox et al. further teaches that it has been further discovered that combinations of silver or silver salts with other antimicrobials provide improved antimicrobial efficacy, such that lower levels of the other antimicrobial agents can be provided (see column 1, lines 25-33 and column 2, lines 30-45, in particular.) Thus, motivation has been provided by Fox et al. to combine two antimicrobial. Particularly since the biguanide polymer is generally useful and the addition of silver salts improve antimicrobial efficacy. In re Kerkoven applies to the above combination because Morlet teaches the antibacterial film with the Applicant's biguanide polymer that can be combined with other antibacterial agents, and Fox teaches silver salts as an effective antibacterial that increases the efficacy of other antibacterial compositions. Thus both references teach topical antibacterial compositions those are proper to be applied to In re Kerkoven.

> The Applicant argues that the Examiner points to Fox's statement that the silver salts exhibit synergistic effects with other antimicrobials as motivation to combine each of Fox, Morlet, and Smith. However, this teaching in Fox is not as broad or effective as the Examiner suggest. Fox provides the closed list of antibiotics selected from cephalosporin, a beta-lactam, an aminoglycoside antibiotic or a quinoline antibiotic (see column 1, lines 40-44). These antibiotics are distinct from the polycationic antibiots of the present invention. While the Fox background states to have fount that a combination with "a variety of antibiotics" provide improved antimicrobial efficacy, this does not extend to all antibiotics. Thus a person of ordinary skill in the art by his own knowledge or upon reading Fox would not consider that each and every antimicrobial combined with a silver salt would have a synergistic effect. There in nothing in Fox to suggest combining the silver salt with any antimicrobial other than the piperazine-substituted naphthalene, piperazine-substituted naphthyridine, and indole/thiazole compound taught by Fox.

The Examiner disagrees because although specific antibiotics are claimed, the Fox reference is taken as a whole. Fox teaches that the antibiotic component of the invention may be any antibiotic which is found suitable for use in topical ocular applications (see column 1, lines 52-53). The variety of antibiotics that the Fox reference refers to is therefore any antibiotic which is found suitable for use in topical ocular applications. The prior art need not show an example for every antibiotic known, but has provided a few as stated by the Applicant.

> The Applicant argues that there is not reason provided either in Smith, Morlet, Fox, or available to one of ordinary skill in the art to combine the compositions for deodorizing footwear with both the antimicrobial compounds of Morlet and Fox. Smith teaches that an odor absorber, neutralizer, or perfume may be used in the complex (col. 3, lines 31-37). There is no suggestion to combine this complex with an antimicrobial metal material. Smith teaches that his composition is effective and has a

> lasting effect (see col. 3, lines 21-25). The above teaching is a disincentive to add further antimicrobials since it is already taught to be effective and long lasting. It is therefore counterintuitive to consider adding an antimicrobial agent such as a metallic material based on Smith or the knowledge of one of ordinary skill in the art. Neither Morlet nor Fox form a film that is moisture resistant and has persistent antimicrobial activity. It is not obvious to combine the teaching of one reference for a method of using a composition (Morlet, PHMB) with another reference teaching the use of the compound for a different purpose (Smith, PHMB) while simultaneously adding an agent from another composition (Fox, Ag).

The Examiner disagrees because Smith teaches forming complexes of antimicrobial compounds that are less water soluble and more hypoallergenic (see abstract and column 1, lines 10-20). Smith teaches that the complexes desirably form a more insoluble higher molecular weight molecule that possess the full activity of the smaller molecule, but are more resistant to being washed away, more hypoallergenic, and longer lasting, and thus allow a larger lasting effect without having to use the antimicrobial agent in higher dosages (see column 3, lines 1-25). In particular, polyhexamethylene biguanide hydrochloride is taught as one of the compounds to form the complex (see column 2, lines 34-38). Thus teaching a film that is water-resistant and has persistent antimicrobial activity is taught with the applicant's elected compound. Additionally, since Fox teaches that combinations of silver or silver salts with other antimicrobials provide improved antimicrobial efficacy, such that lower levels of the other antimicrobial agents can be provided (see column 1, lines 25-33 and column 2, lines 30-45, in particular), it would be obvious for the above reason to add silver salts to the complex. In regards to the combination of Morlet, Smith and Fox, they all teach antimicrobial compositions, thus are proper to combine.

Claims 65-67, 91, 94, 97, 104,107, 115-116 and 125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morlet et al, in view of Fox, Jr., issued Smith as applied to claims 58, 60, 62-64, 68-71, 89, 92, 93, 96, 98-103, 105-106, 108-114 and 117-124 above, and further in view of Sawan et al.

> The Applicant argues that just because WO'152 teaches both a dispenser and that solutions can be placed in the dispenser does not make any combination of the dispenser properties and the properties of any solution that may go into the dispenser obvious. WO'152 provides a dispenser having antimicrobial properties so that microbes within a solution in the dispenser (and therefore placed in contact with the coated walls of the dispenser) will be destroyed. Once the solution is removed from the dispenser (i.e., to be used as an eye rinse), no antimicrobials from the dispenser remain with the solution. This is an important aspect of the WO'152 publication since it provides a solution without microbial contaminants but without any antimicrobials in the solution. While the adduct can be contacted with solutions and these solution can later contact the human body, the solutions do not provide antimicrobial effects. The dispenser does. While a Teflon-coated pan is used as a non-stick cooking surface, this use does not make it obvious to use Teflon in a lotion to keep skin from sticking.. The substrates are completely different. Thus, it would similarly not be obvious to use the coating for the dispenser on skin.

The Examiner disagrees because as discussed above, Smith clearly teaches the benefits of the polyhexamethylene biguanide in antimicrobical compositions. Additionally, Sawan et al. teaches that polyhexamethylene biguanide is a known antimicrobial agent that can be provided in derivatized form, and further exemplifies forming antimicrobial coating containing a derivative of polyhexamethylenebiguanide

that is an adduct thereof. While Sawan et al. does not specifically teach providing the polyhexamethylene biguanide adduct into a solution, Sawan et al. does teach that the coatings can be contacted with solutions, such as eye care solutions, to sterilize them. Thus, Sawan et al. teaches that the adduct itself can be safely contacted with solutions meant for application to the human body to provide antimicrobial effects. Sawan et al. also teaches that silver iodide can be provided in such solutions to sterilize them. Thus, the biguanide adduct and silver iodide provide antimicrobial effects. Additionally, silver metals and polyhexamethylene biguanide itself or in a complex have been shown to be used in solutions that come in contact with the human body. Therefore, one can not separate the properties of the compounds. "Products of identical chemical composition can not have mutually exclusive properties." Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product. Accordingly, it is considered that one of ordinary skill in the art would have found it obvious to provide the biguanidine adduct as taught by Sawan et al. in the composition of Morlet et al, Fox and Smith, with the expectation of providing a suitable antimicrobial composition.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 7:30-4:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KDC

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